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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/538,292

06/10/2005

Michael Howard Rayner-Brandes

MERCK-3006

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09/18/2008

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EXAMINER

WOOD, ELLEN S

ART UNIT

PAPER NUMBER

1794

MAIL DATE

DELIVERY MODE

09/18/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/538,292	Applicant(s) RAYNER-BRANDES ET AL.	
	Examiner ELLEN S. WOOD	Art Unit 1794	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 June 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 and 13-22 is/are pending in the application.
- 4a) Of the above claim(s) 10-12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 and 13-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 June 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>06/10/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's election with traverse of Group 1, claims 1-9 in the reply filed on 06/25/2008 is acknowledged. The traversal is on the ground(s) that the combination of the re-sealable strip device and the process for the drying and storage of viable micro-organisms does not lack unity of invention. This is not found persuasive because the process in which is used to store and dry the micro-organisms includes technical features such as requiring opening an access window that are not technical features for the actual strip device, thus the two inventions lack the same technical features. Thus, the combination of the re-sealable strip device and the process for the drying and storage of viable micro-organisms lacks unity of invention.

The requirement is still deemed proper and is therefore made FINAL.

EXAMINER NOTE: With the new claims entered Group 1 are claims 1-9 and 13-22, thus the kit will be included as part of Group 1.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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3. Claims 1-7, 13 and 15-21 are rejected under 35 U.S.C. 102(e) as being anticipated by Schoedel (US 6,927,062).

In regards to claim 1, Schoedel discloses a strip device for drying and storing micro-organisms (abstract). The porous carrier material is adhered to the distal end of a support member to form a strip (col. 3 lines 53-55). The porous carrier material is considered the primary water absorbent preparation. The porous carrier material contains at least one water absorbent substance and at least one protective substance (col. 4 lines 53-58). The applicant discloses that protective substances include carbohydrates, polymers, peptides, and protein based preparations and fractions (pg. 10 lines 17-24). Thus, the examiner considers the proteins listed by Schoedel to be the protective substance. The control strips can be stored in a ZIPLOCK bag which is impervious to light and moisture (col. 12 lines 55-57). Thus, the bag is re-sealable.

In regards to claim 2, Schoedel discloses that the porous carrier material contains is pre-treated with a solution that contains sucrose (col. 5 lines 20-25). The applicant discloses that a water absorbent substance that additionally shows properties of a protective substance is sucrose (pg. 11 lines 6-10). Thus, the examiner considers the sucrose in the pre-treatment solution of Schoedel to be a substance that contains both water and protective properties.

In regards to claim 3, Schoedel discloses that the porous carrier material can comprise and water insoluble porous material commonly used for absorbing analytes (col. 10 lines 7-9). The preferred porous carrier material comprises glass or synthetic fibers (col. 10 lines 12-15).

In regards to claim 4, Schoedel discloses that a desiccant can be disposed within the container (col. 12 lines 53-55), thus within proximity to the primary water absorbent preparation. The examiner considers the desiccant to be the secondary water absorbent preparation.

In regards to claims 5, Schoedel discloses that a desiccant can be disposed within the container (col. 12 lines 53-55). Thus, the second water absorbent preparation is in proximity to the primary water absorbent preparation (fig. 1B).

In regards to claims 6-7, Schoedel discloses the control strips can be stored in a pouch such as a foil-lined plastic ZIPLOCK bag which is impervious to light and moisture (col. 12 lines 55-57).

In regards to claim 13, Schoedel discloses a kit (col. 12 lines 48-51) that comprises a re-sealable strip device and a solution that is incorporated into the porous carrier material that reduces the likelihood of substantial degradation of the analyte over time (col. 10 lines 35-37).

In regards to claims 15-16, Schoedel discloses that the porous carrier material is adhered to the distal end of a support member to form a strip (col. 3 lines 53-55). The support member preferably comprises a polymer or other non-absorbent material such as plastic card stock (col. 12 lines 24-26).

In regards to claim 17, Schoedel discloses that porous carrier materials were adhered to plastic card stock and once the entire length of the adhesive area of the card stock had carrier materials the plastic card stock was cut (col. 19 lines 4-11). Thus, the primary porous carrier material is in proximity to a secondary porous carrier material.

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In regards to claim 18, Schoedel discloses that at least one of the protective substance is a carbohydrate (col. 11 lines 14-16).

In regards to claim 19, Schoedel discloses the pre-treatment solution may comprise a protein (col. 10 lines 47-50).

In regards to claims 20-21, Schoedel discloses that the pretreatment solution comprises sucrose as the preferred carbohydrate (col. 10 lines 56-57) and a phosphate buffer (col. 11 lines 16-19).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 8-9 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schoedel (US 6,927,062).

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In regards to claims 8-9, Schoedel discloses the re-sealable strip device for drying and storage of micro-organisms as described in the previously. Schoedel is silent with regards to the placement of the label and a secondary peel or tear seal which can be opened. Schoedel discloses that there is identifying information taped to the non-adhesive area of the plastic card stock (col. 19 lines 6-7). Schoedel provides this conventional teaching showing that it is known in the art to use labels on plastic substrates. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to make the label on the re-sealable housing unit motivated by the substrates being of similar material and providing the consumer with the nature of the contents of the container. It would be obvious to one of ordinary skill in the art that depending on the use of the strips various pouch configurations may be used, including one with an additional tear strip, which provides a way to protect the consumer from infection from the micro-organisms.

In regards to claims 14 and 22, Schoedel discloses that a desiccant is disposed within the package (col. 12 lines 53-55). It is known to one of ordinary skill in the art that the most commonly used desiccants are silica gel and molecular sieves. It is also known that desiccants are used to absorb water, thus it would be obvious that the desiccant contains at least one water absorbent substance.

Response to Amendment

7. The amendments and new claims, 14-22, have been entered.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELLEN S. WOOD whose telephone number is (571)270-3450. The examiner can normally be reached on Monday-Friday 7-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carol Chaney can be reached on 571-272-1284. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ellen S Wood
Examiner
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/Carol Chaney/

Supervisory Patent Examiner, Art Unit 1794